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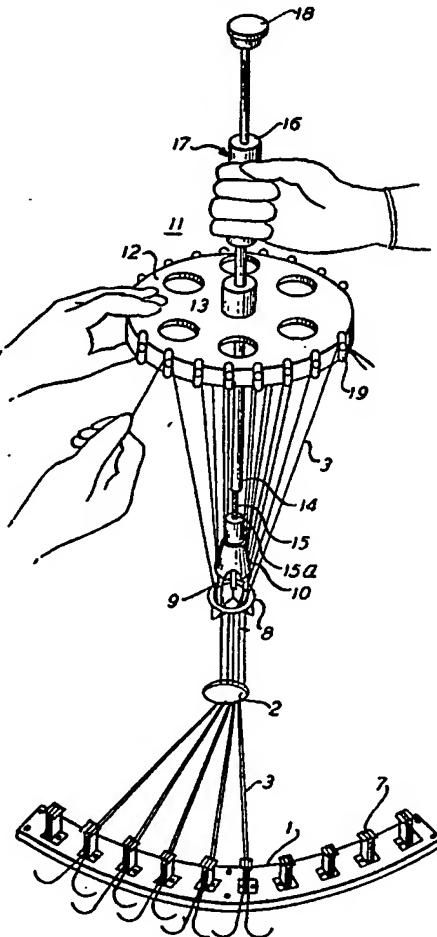
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GB 1127325
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(54) Prosthetic device holder, and suture organizer

(57) A heart valve holder has a plurality of circumferentially spaced legs 9, to which an artificial heart valve can be releasably held by sutures 3. Legs 9 depend from an internally threaded holder 10 formed for co-action with a rod 14 slidably positioned in a holding disc 13 which carries spring clips 19 about its circumferential edge for releasable co-action with the sutures

used to secure the valve in place. Suture organizers 16 each formed with an arcuate support member upon which a selected number of suture holding devices 7 are provided to be disposed proximate an area of a body. Each holding device 7 includes a pair of spaced wall members and a resilient holding member disposed in compression therebetween in such a manner that sutures can be releasably held between the resilient member and the adjacent wall member surface.

FIG. 4



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FIG. 1

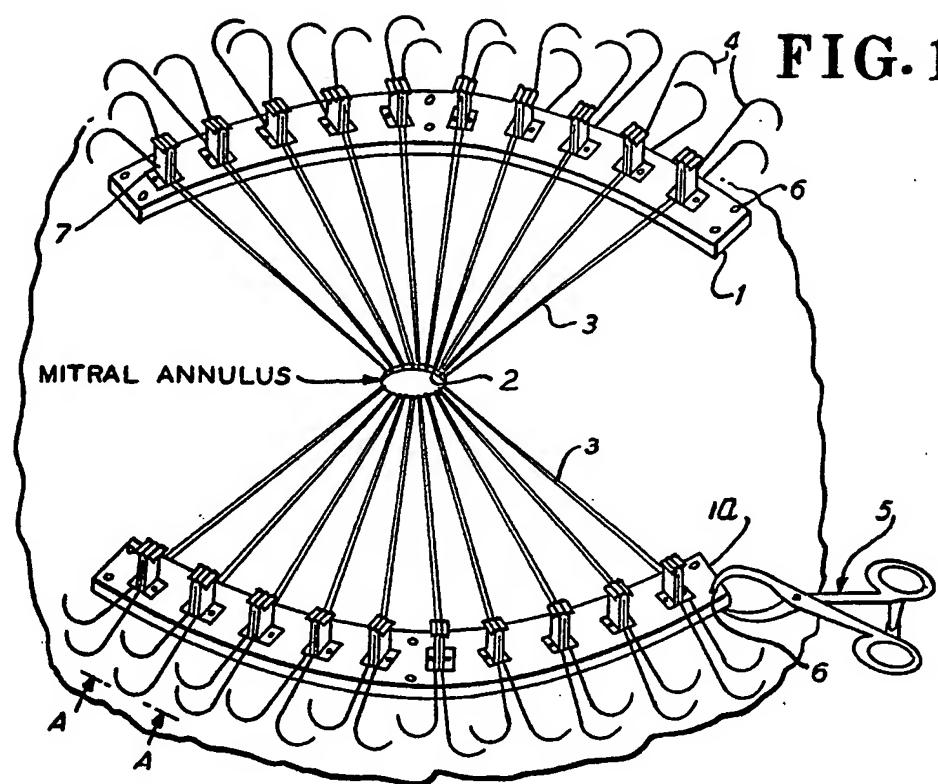
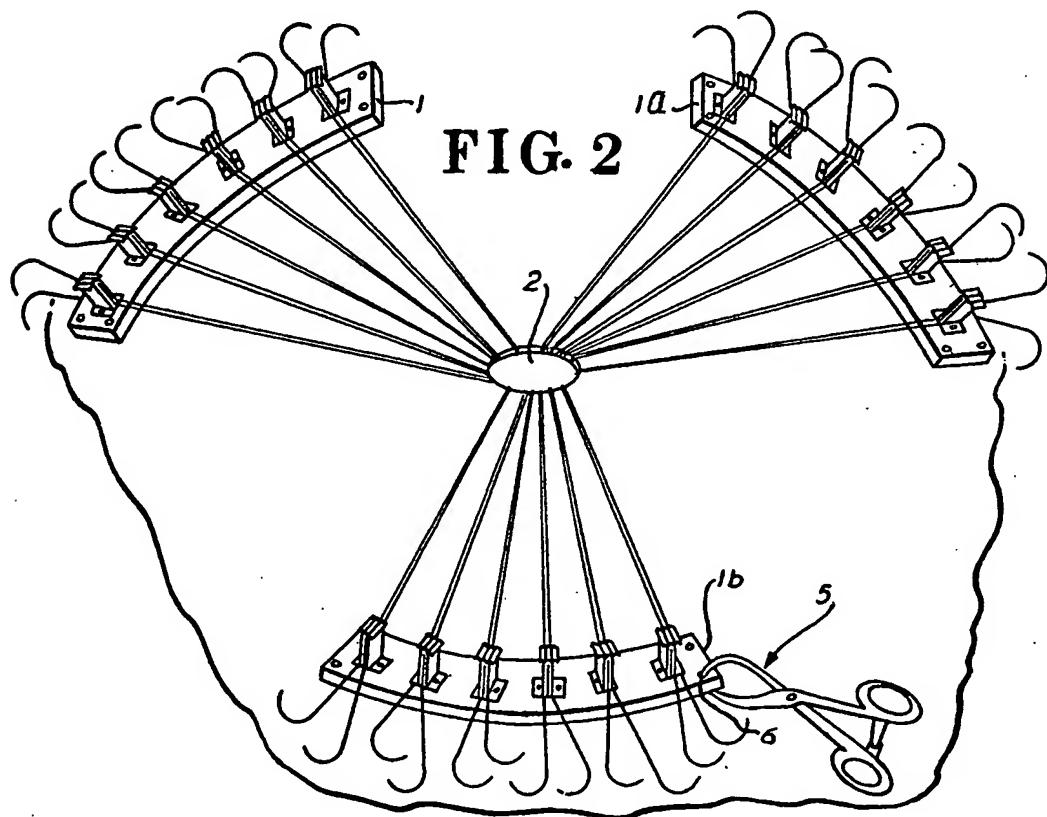


FIG. 2



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FIG. 4

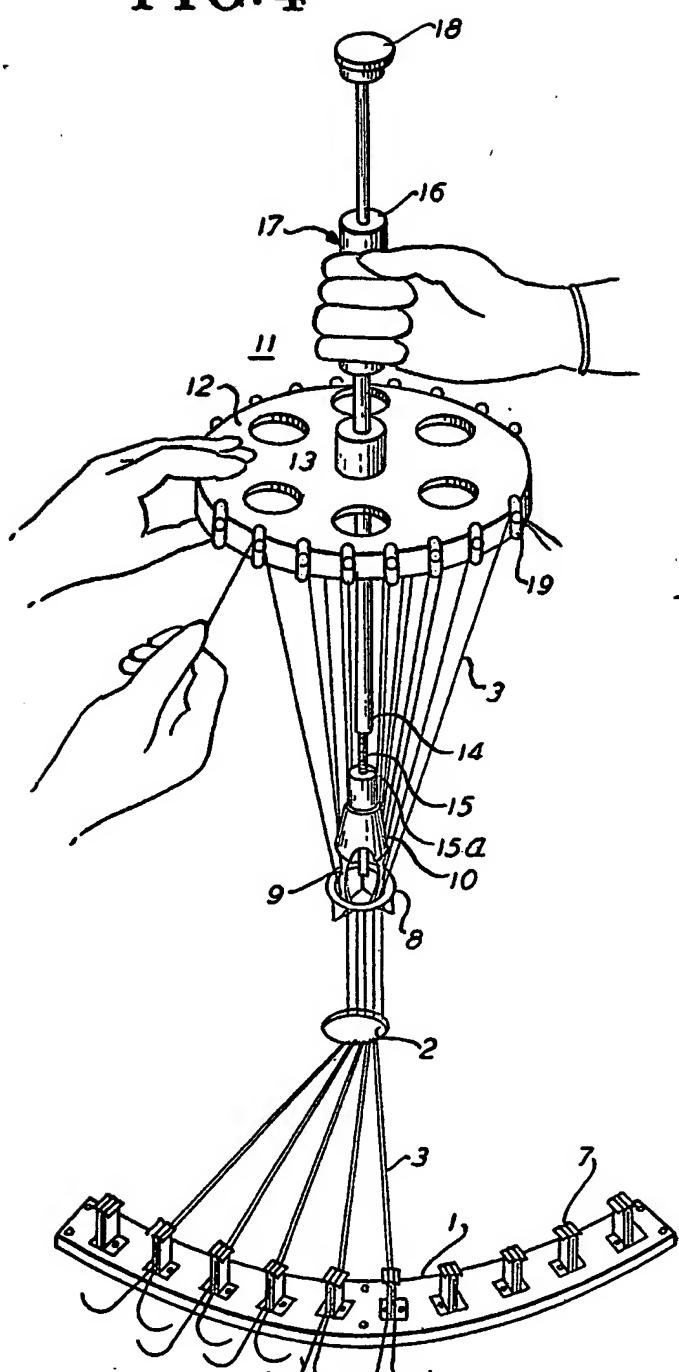


FIG. 3

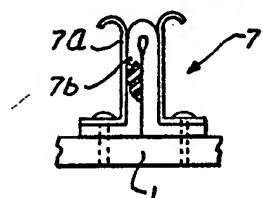
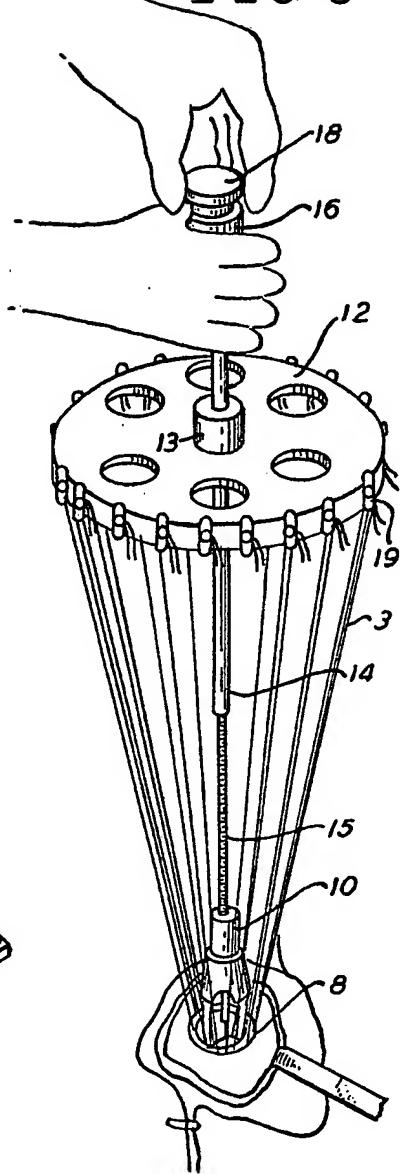
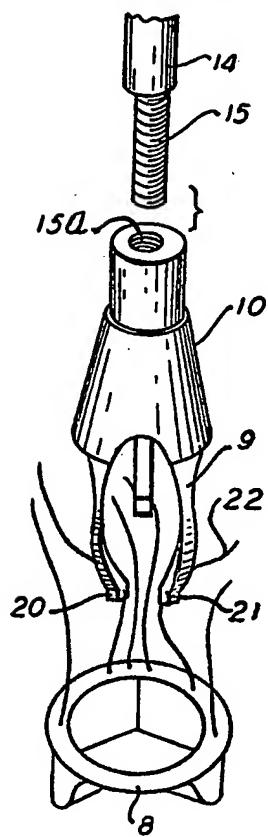


FIG. 5



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FIG. 8



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FIG. 6

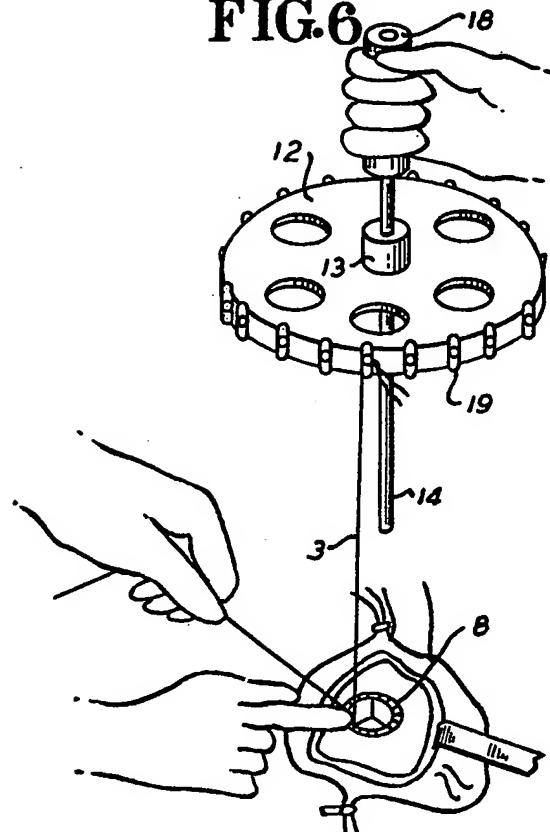


FIG. 9

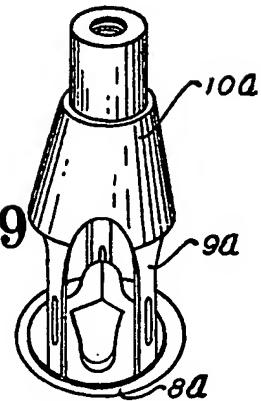
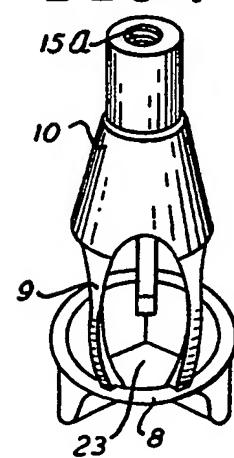


FIG. 7



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FIG.10

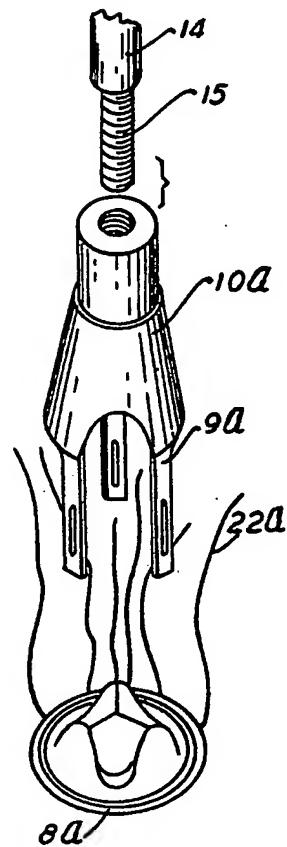


FIG.11

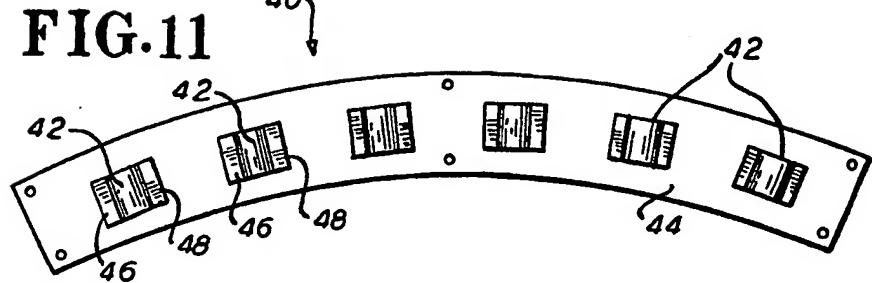
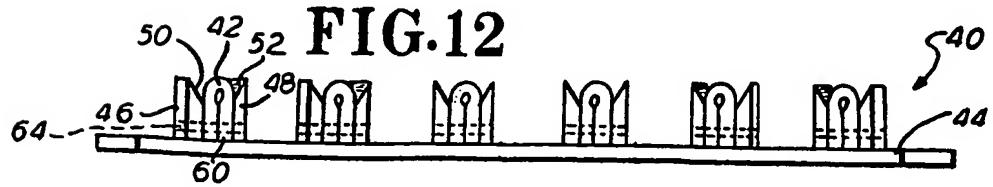


FIG.12



SPECIFICATION

Suture organizer, prosthetic device holder, and related surgical procedures

5 This invention relates to surgical procedures and devices utilized to facilitate speedy and orderly surgical procedures; and more particularly to holders for sutures and prosthetic devices and related surgical procedures.

10 The time consumed in completing a serious medical operation, particularly operations which involve the exposure of the internal body cavity, is of extreme importance to the survival of the patient. Experience has shown that there is a direct relationship between the time span of the operation and its success.

15 The above factors are particularly true in connection with such serious operations as open-heart surgery where there is not only the problem of exposure but which involves the use of artificial/mechanical means for maintaining the vital functions of the patient during the operation. In such operations, one of the more time-consuming steps involved in replacing a defective heart valve with an

20 25 artificial valve is the attachment of the valve to the heart by means of multiple sutures, and this, of course, during the time when the patient is relying upon outside artificial means to sustain his or her life. During aortic valve replacement, the heart itself

30 35 is cut off from the general circulation and is thereby denied the oxygen and nutrients it needs to maintain its integrity as a living tissue. During mitral valve replacement, some perfusion of the heart muscle is maintained, but not at an optimal level. Thus there are compelling advantages to keeping the heart muscle at risk for only the shortest possible time span.

40 During the type of operation above described, it may be necessary to connect the artificial valve to the natural annulus of the heart valve by twenty or more sutures, all of which will eventually be projecting from the site of the attachment; which is a relatively small space. Consequently, it often becomes very difficult to keep the individual sutures separated, and valuable time may be lost in doing so, and in locating the proper suture pairs which are to be tied and knotted.

45 It is also imperative to keep count of the needles utilized in sewing the sutures since all such needles must be accounted for before the body cavity is closed. The search for lost needles prolongs the time of the surgery and adds additional risk for the patient.

50 The proper positioning of the prosthetic device being implanted is also quite essential if the surgical procedure is to be successful. Placement by hand is often difficult if not impossible due to the size of the device to be implanted, the restricted size of the area of implant and the conditions surrounding same.

55 60 The use of complex holding devices facilitates the space problem, but often increases the time of the operation with attendant concerns.

65 This invention involves surgical procedures requiring the use of multiple interrupted sutures, and especially surgical procedures for anastomoses and

implantation of artificial heart valves; and contemplates providing one or more organizers for releasably holding sutures and associated needles in a selected, orderly and controlled arrangement; providing a holder for releasably holding and positioning the prosthetic device for implantation; with related surgical procedures.

70 In carrying out the invention, according to the preferred embodiments each organizer is formed to

75 80 carry a plurality of holders each, in turn, formed to releasably accept and readily release either or both ends of an interrupted suture; the prosthetic device holder includes a number of depending arms which resiliently grip the prosthetic device and to which the prosthetic device may be sutured; and the surgical procedures utilize one or more of such organizers and prosthetic device holders.

85 Other objects, features, and advantages of the invention in its details of construction and arrangement of parts will be seen from the above, from the following description of the preferred embodiment when considered in conjunction with the drawings and from the appended claims.

90 In the drawings:

95 FIG. 1 is a plan view of a pair of suture organizers or retractors, incorporating the instant invention; FIG. 2 is a plan view illustrating a modified form and arrangement of suture organizers; FIG. 3 is an enlarged view of an individual suture holder; FIG. 4 illustrates the use of a suture holder as shown in FIG. 1, together with a valve and suture holder device also incorporating the instant invention;

100 FIG. 5 and 6 illustrates sequential steps taking place during the implantation and suturing of an artificial valve following the initial step illustrated in FIG. 4; FIG. 7 illustrates the combination of a mitral valve and valve holder in accordance with this invention; FIG. 8 illustrates the disconnection between the valve holder and the artificial mitral valve; FIG. 9 and 10 are similar to FIGS. 7 and 8, showing an artificial aortic valve;

105 FIG. 11 is a plan view of a further modified form of suture organizer incorporating the instant invention; and FIG. 12 is an elevational view of the suture organizer of FIG. 11.

110 According to the invention as shown in FIG. 1, individual suture holders (to be hereinafter described in detail) are maintained by suitable and conventional means upon arcuately shaped supports or organizers 1 and 1a which will be placed

115 120 upon the body of the patient (not shown) but on substantially opposite sides of the situs of the operation which in this case may be the mitral annulus 2. Multiple sutures 3 are threaded about the circumference of the annulus and for this purpose are preferably provided with needles 4. Except for the space immediately surrounding the situs of the operation, the body of the patient is generally covered with toweling or other suitable material and the frame 1 and 1a are sufficiently held in place by clamping to

125 130 these towels through the use of a clamp 5 which may

engage the frames through the use of openings 6. While frames 1 and 1a are shown as arcuate, other suitable configurations may be used.

Instead of utilizing two organizers, as illustrated in FIG. 1, it may for certain purposes be more convenient to utilize three or more such organizers as illustrated in FIG. 2, at 1, 1a and 1b.

The construction of the individual suture holders 7 (FIG. 3) is of extreme importance in that they must firmly engage the sutures against lateral motion but must also permit the individual sutures to be quickly disengaged as by an upward motion therefrom. To that end, each individual suture holder is formed by a pair of spaced, preferably stainless steel or plastic, 15 spring arms 7A between which is compressed a piece of soft rubber bent back upon itself, indicated at 7B. The combination of steel and soft rubber making up each individual suture holder is attached to frame 1 by suitable means such as bolts or rivets 20 from frame 1.

FIG. 4 illustrates an assisting device for use in the attachment of an artificial valve 8 to the annulus 2 of a diseased heart valve, and, as is shown, it is assumed that the diseased natural valve has already 25 been removed; the patient at this point being maintained by artificial means such as an external heart-lung machine. The basic sutures 3 are now in place and are being held by the individual suture holders 7 mounted on frame 1. The mitral valve 8, to be 30 attached to the annulus 2, is temporarily attached by sutures 3 to the arms 9 extending from a disposable plastic valve holder 10. Holder 10 may be made from plexiglass (Trade Mark) or other suitable material, and it is contemplated that valve holder 10 and the 35 valve 8 may be a preconnected unit individually packaged and supplied to the surgeon. The combination of valve 8 and valve holder 10 is illustrated in more detail in FIGS. 7-10 and will be described in more detail hereinafter.

40 The application and attachment of artificial valve 8, to the annulus 2 of the diseased valve is preferably effected through an assisting device generally indicated at 11 in FIG. 4, consisting first of a plastic disk 12 provided with an integral hub 13 through which 45 may be slidably moved, a rod 14 preferably of stainless steel and provided with an externally threaded projection 15 engaging an internally threaded opening 15a in the top of disposable valve holder 10. Spaced above and integral with hub 13 is a hand grip 50 16 having a threaded opening into which a set screw 17 is threaded. The upper end of rod 14 is provided with a knob 18.

A plurality of spring clips 19 are attached about the outer periphery of the disk 12 for holding sutures 3 in 55 a manner hereinafter described.

Disposable valve holder 10 and its attached mitral valve 8 are illustrated in more detail in FIGS. 7 and 8, from which it will be seen that legs 9 extending from valve holder 10 have cut-out portions 20 engaging 60 the inner periphery of valve 8, legs 9 additionally being formed with openings 21 by means of which the valve 8 and valve holder 10 are joined together by sutures 22. Thus the initial unitary structure consists of valve holder 10 and valve 8 to be later dis- 65 connected as more clearly illustrated in FIG. 8. Valve

8 is provided with the usual valve cusps 23 which may be made of suitable material and in the present form may actually be the valve cusps removed from an animal such, for example, as a pig.

70 FIGS. 9 and 10 are similar to FIGS. 7 and 8 but illustrate the combination of a disposable valve holder 10a with an aortic valve 8a. In this form of the invention, legs 9a of valve holder 10a may be straight and form a unit with valve 8a by attachment 75 with sutures 22a.

The manner in which the apparatus described above is utilized in an actual operation will now be described in more detail with particular reference to FIGS. 4, 5 and 6.

80 As shown in FIG. 4, disk 12 supporting unitary valve and valve holder 8 and 10 is being held directly above mitral annulus 2, some of the sutures 3 remaining in holder 10 while others have already been threaded through valve 8 and are supported on disk 12 by the spring clips 19. In FIG. 5, the valve is shown in place, having been pushed downwardly by rod 14 and sutures 3 attach valve 8 to annulus 2 and are all retained on clips 19 of disk 12. By loosening set screw 17 and rotating knob 18, threaded extension 15 of rod 14 is removed from the top of valve 8 and disposable valve holder 10 is discarded, leaving valve 8 in place. As shown in FIG. 6, the operation is substantially over, all sutures 3 but one having been tied and valve 8 is firmly in place, having been 95 attached to the heart and more specifically to annulus 2.

Obviously the same procedure is used in replacing the aortic valve except that in this case valve 8a and disposable holder 10a are utilized.

100 FIGS. 11 and 12, illustrate a suture organizer 40 upon which are secured a number of suture holders 42 of alternative configuration. Organizer 40 is formed with a support 44 of suitable plastic such as Delrin (Trade Mark) upon which there is disposed a number of spaced holders 42, each including a pair of spaced arms 46 and 48. Arms 46, 48 are inflexible, and if formed of the same material as support 44, may be cast integral therewith. Arms 46, 48 may also be formed of other suitable material, such as stainless steel or the like, and suitably secured together as by screws, bolts or rivets. Each arm 46, 48 is cut 105 diagonally and inwardly along its top, as shown at 50, 52 respectively to facilitate insertion of a suture between the inwardly facing wall or arms 46, 48 and an insert 60 of resilient material. Insert 60 may be formed from rubber or plastic and can be cut from either tubular material or flat stock as long as such is of proper thickness so that the tube, or flat stock when folded upon itself, will fill the space between arms 46, 48 and be compressed therebetween so that the sides of insert 60 about the inside walls of arms 46, 48, and exert a pressure thereagainst sufficient to releasably hold the sutures between insert 60 and the inside walls of arms 46, 48. If desired a pin, rivet or other suitable means 64, may be passed between arms 46, 48 and through insert 60 to secure same in place.

110 While the suture organizers shown in FIGS. 1 and 2, 11 and 12 are particularly useful in the replacement of heart valves and more particularly with the

115 120 125 130

120 125 130

120 125 130

apparatus shown in FIGS. 4, 5 and 6, it will be apparent to those skilled in this art that they are extremely useful in supporting and separating multiple interrupted sutures in any operation where such multiple 5 suturing is required as, for example, in the re-section of the small intestine, the anterior resection of the colon, the repair of the coarctation of the aorta and the repair of indirect inguinal hernia; the utility of the invention, however, is not limited to the examples 10 given.

With respect to the disposable prosthetic device holder and the apparatus described and illustrated for performing the operation, variations in specific details are contemplated. For example, the number 15 of legs projecting from the body of the holder may be varied and differently positioned depending upon the shape of the prosthetic device, i.e., as for a semi-lunar valve.

From the above description it will thus be seen 20 that novel and improved suture organizers, and prosthetic device holders, have been shown with attendant surgical procedures; all of which are simple, efficient and most important serve to reduce the time required for surgery in operations where time is 25 a critical factor.

CLAIMS:

1. Prosthetic device positioning apparatus; comprising:

- a) a support having a central opening there- 30 through;
- b) a plurality of suture holders mounted about the periphery of said support;
- c) a rod slidably supported in said opening;
- d) a prosthetic device holder, formed to detach- 35 ably hold and position a prosthetic device, mounted on one end of said rod such that sliding movement of said rod with respect to said support serves to position a prosthetic device for disposition on a patient when a prosthetic device is held by said 40 apparatus and the apparatus is utilized during surgery.

2. The apparatus of claim 1, wherein said support is disk shaped.

3. The apparatus of claim 2, wherein said suture 45 holders are in the form of spring clips disposed about the periphery of said disk.

4. The apparatus of claim 1, wherein said prosthetic device holder includes a plurality of legs extending downwardly and formed to detachably 50 hold a prosthetic device.

5. The apparatus of claim 4, wherein said prosthetic device is a heart valve.

6. The apparatus of claim 1, wherein said end of said rod is provided with a threaded extension, and 55 said holder is threaded on said extension, whereby said holder may be removed from the end of said rod.

7. The apparatus of claim 1, wherein said disk is provided with an integral handle portion concentric 60 with said central opening, a set screw extends through said handle portions abutting at its inner end against and slidably rod, and a knob is disposed at the end of said rod opposite the device holder.

8. The apparatus of claim 1, wherein at least one 65 organizer for multiple sutures is formed to be placed

for coaction with said apparatus during an operation in such a manner that sutures utilized during the operation may extend from said suture organizer through the patient and onto said suture holders 70 mounted about said support.

9. A suture holder and organizer; comprising:

- a) a base member;
- b) at least one pair of spaced arms extending upwardly from said base member;

75 c) resilient means disposed in said space between said pair of said spaced arms so as to be compressed therebetween but so as to permit the releasable insertion of a suture between said resilient means and a surface of one said arm proximate said resilient means.

10. The organizer of claim 9, wherein there are a plurality of pairs of spaced arms extending upwardly from said base member with resilient means so disposed between each such pair of spaced arms.

85 11. The organizer of claim 10, wherein said resilient means consists of a strip of rubber like material folded upon itself and sized to fill said space between said spaced arms so as to be compressed therebetween.

90 12. The organizer of claim 11, wherein said spaced arms each includes a lateral extension secured to said base member and said resilient strips each include lateral extensions disposed between the associated lateral extensions of said spaced arms and which are secured in place with said lateral extensions of said spaced arms.

13. The organizer of claim 10, wherein said spaced arms are flexibly secured to said base member.

100 14. The organizer of claim 10, wherein said spaced arms are rigidly secured to said base member.

15. The organizer of claim 10, wherein the tops of each of said spaced arms are cut-off on a slant

105 inwardly towards said space therebetween.

16. The organizer of claim 10, wherein said resilient means is formed from a piece of tubular material cut and otherwise sized to be compressed between said spaced arms.

110 17. The organizer of claim 16, wherein securing means are provided for securing said resilient means in place between said spaced arms.

18. The organizer of claim 10, wherein said base member and spaced arms are formed as a unit from 115 plastic material.

19. The organizer of claim 18, wherein said plastic material is Delrin.

20. A disposable heart valve unit; comprising:

- a) a valve holder having a central threaded core at 120 one end and a plurality of separate projecting legs at the other end;

b) an artificial heart valve comprising an annular ring and inwardly positioned flaps attached to said rings; and

125 c) sutures attaching the ends of said legs to said annular ring.

21. The disposable heart valve unit of claim 20, wherein the ends of each of said legs are provided with an opening therethrough, the ends of said legs 130 being annularly spaced at a diameter equal to the

inside diameter of said annular ring, and said sutures extend through the surface of said ring and said holes, whereby the valve holder and heart valve comprise a separable unitary structure.

5 22. The disposable heart valve unit of claim 21, wherein said heart valve is a mitral valve and in which the ends of each of said legs are provided with an inward notch abutting the inner surface of said annular ring.

10 23. A surgical procedure comprising the steps of:
a) placing at least one suture organizer, with a plurality of suture holders each for releasably holding a suture disposed thereon, in proximity to the area of a patient upon which there is to be surgery;

15 b) passing a first suture through a selected area of the patient and inserting its ends into a first one of said suture holders;
c) passing additional sutures through other areas of the patient in a selected order and inserting the 20 ends of said additional sutures in consecutive suture holders;
d) selectively releasing said sutures, one by one and in a predetermined order; and
e) tying said sutures in said selected and pre-
25 determined order;

24. The procedure of claim 23 including the step of cutting the sutures to selectively release same.

25. The procedure of claim 23 including utilizing a second suture organizer in a manner similar to said 30 first suture organizer.

26. The procedures of claim 25 including the step of utilizing a third suture organizer in a manner similar to said first and second suture organizer.

27. The procedure of claim 26 including the steps 35 of:
a) providing a prosthetic device holder with means for positioning a prosthetic device for implantation into a patient;
b) releasably securing a prosthetic device to said 40 prosthetic device holder;
c) further providing said prosthetic device holder with suture holding means; and
d) threading sutures through a prosthetic device, while held by said prosthetic device holding means,
45 and releasably positioning selected ends of said sutures in selected ones of said suture holding means.

28. The procedure of claim 27 including the steps of utilizing said prosthetic device holder to position a 50 prosthetic device and releasing said prosthetic device from said prosthetic device holder when so positioned.

29. The procedure of claim 28, wherein said 55 releasable securing of said prosthetic device to said prosthetic device holder includes the steps of threading suture through said device and holder.